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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,177	CATES ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-18,20 and 21* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Claims

1. Claims 1-21 were pending and rejected in the prior office action, mailed on March 26, 2003. In the Response, filed on September 24, 2003, claim 3 was amended, and claim 19 was cancelled. Currently, claims 1-18, 20, and 21 are pending and under consideration.

Specification

2. **(Prior Objection- Withdrawn)** The disclosure is objected to for informalities in the specification. In view of the amendment to the specification, the objection is withdrawn.

3. **(Prior Objection- Maintained)** The use of the trademark Fluzone® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. In the present case, the applicant has identified the term as a trademark by use of the ® symbol, but has not described the generic composition of the Fluzone vaccine. An example of such a generic descriptor is an identification of Fluzone® as an influenza vaccine.

Applicant's argument that a description of the making of the vaccine is present in the application is noted. However, as indicated by MPEP § 6.20, the generic descriptor is to appear with each instance of the use of the trademarked name. Thus, the presence of the description alone is not sufficient because there is no generic terminology accompanying each instance of the use of the term Fluzone®.

It is further noted that on page 17, lines 23 and 24, two instances of the term Fluzone appears with no capitalization or ® mark, and with no generic terminology as indicated above. Thus, amendment is required to insert generic terminology with each instance of the Fluzone ® mark, and to correct the instances in application where neither an indication of the proprietary nature of the mark (capitalization or ®) or generic terminology is provided with the use of the tradename.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(Prior Rejection- Withdrawn) Claims 3 was rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition comprising an adjuvant wherein there is an enhanced immune response to the claimed composition when compared to the composition of the adjuvant and RSV component without the influenza component where the adjuvant is PCPP and the influenza preparation is FLUZONE®, does not reasonably provide enablement for a composition comprising any adjuvant or any influenza preparation with such effects. In view of the amendment to the claim, the rejection is withdrawn.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **(Prior Rejection- Withdrawn)** Claim 19 was rejected in the prior action for indefiniteness. In view of the cancellation of this claim, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

7. **(Prior Rejection- Maintained)** Claims 1, 2, 5-18, and 20 were rejected in the prior action under 35 U.S.C. 103(a) as being obvious over Cates et al. U.S. Patent 6,020,182 (Cates U.S.), in view of Smith et al., U.S. Patent 5,762,939, and Webster et al., U.S. Patent 5,824,536. Claim 1 describes immunogenic compositions comprising fusion (F), attachment (G), and matrix (M) proteins of respiratory syncytial virus (RSV), and an immunoeffective non-virulent influenza virus preparation. The other claims either further identify the claimed composition, or describe a method of using such to immunize a human against diseases caused by these viruses. As indicated in the prior action, the Cates reference teaches an RSV vaccine and the combination of this vaccine with other immunogenic compositions, including those targeting influenza. Also as indicated in the prior action, Smith teaches an influenza vaccine, and Webster teaches preferred dosages of the

The Applicant traversed this rejection in the Response on two grounds. First, the Applicant asserted that Cates U.S. provides no motivation to select influenza out of the list of other antigens that may be used with the disclosed RSV vaccine. Second, the Applicant argued that one skilled in the art would not have had a reasonable expectation that the two vaccine formulations (RSV and influenza) would be effective when combined.

The first argument in traversal is not found persuasive. As indicated in the prior action, Cates explicitly indicates that influenza, among a short list of other antigens, may be used in conjunction with the disclosed RSV formulation. Thus, one skilled in the art, absent specific teachings to the contrary, would have had a reasonable expectation that the disclosed RSV formulation would be operative with the other antigens disclosed by the Cates U.S. reference. As the reference indicates that this antigen may be used in combination with the RSV antigens, there is sufficient motivation in the references (as indicated in the prior action) for the making of the combination. It is noted that the reference indicates that other antigens may also be used. However, this merely renders obvious the combination of the RSV vaccine with any of those other antigens, including the influenza vaccine. As the Applicant has not demonstrated that any unexpected results were achieved through the combination of RSV and influenza vaccines generally, the Applicant has not overcome the prima facie case of obviousness based on the insufficiency of the motivation provided by Cates U.S.

As indicated above, the Applicant's second argument in traversal of the rejection is that one skilled in the art would not have had a reasonable expectation of success in the combination of the RSV and influenza antigens. This argument is also not found persuasive. The Applicant asserts that while there is a tendency in the art to combine vaccines, there is also knowledge in that art that certain combinations may lead to reduced efficacy of one or both of the combined antigens. However, Cates U.S. indicates that the RSV and influenza vaccines could be combined. While the Applicant asserts a general proposition that is understood in the art, no evidence has been presented indicating that those in the art would not have had a reasonable expectation of success in this specific combination. Thus, because the Cates U.S. reference indicates that the

combination would be operative, and because no evidence has been provided to show the combination suggested by Cates U.S. would not be operative, the rejection is maintained. Thus, claims 1, 2, 5-18, and 20 remain rejected for the reasons above and of record.

8. **(Prior Rejection- Maintained)** Claims 1, 2, 5-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates et al., WO 98/02457 (Cates PCT), published Jan. 22, 1998, in view of Smith et al., U.S. Patent 5,762,939, and Webster et al., U.S. Patent 5,824,536. The claims are described above. The Applicant traverses this rejection on substantially the same grounds as indicated above with regards to the rejection over Cates U.S., Smith, and Webster. The rejection is therefore maintained for the reasons indicated above and for the reasons of record.

9. **(Prior Rejection- Maintained)** Claims 1, 2, 4, 6-14, and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S. or Cates PCT as applied to claims 1, 2, 5-18, and 20 above, and further in view of Payne, Vaccine, Vol. 16(1): 92-98. Claims 1, 2, 5-18, and 20 were described above. Claim 4 limits the composition to embodiments wherein the adjuvant is PCPP. The Applicant traverses this rejection on the grounds of an asserted deficiency in the combined teachings of Cates U.S./PCT, Smith, and Webster. For the reasons indicated above, this traversal is not found persuasive. The rejection is therefore maintained.

10. **(Prior Rejection- Withdrawn in part)** Claims 3 and 4 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Cates PCT in view of Andrianov, U.S. 5,494,673. The teachings of the references have been described in the prior action. Claim 4 reads on the multivalent immunogenic composition of claim 1 wherein the composition also includes the adjuvant PCPP. Claim 3 also reads on this composition with the additional requirement that the influenza preparation is the Fluzone® influenza vaccine. The rejection is maintained against claim 4, but withdrawn from amended claim 3.

The Applicant traversed the rejection for substantially the same reasons as indicated in regards to the other obviousness rejections above (i.e. asserted deficiencies in the teachings of the Cates references). The rejection of claim 4 is maintained for the reasons indicated in response to the arguments in traversal above. However, because the Applicant has shown unexpected synergy from the combination of the claims RSV composition, the Fluzone® influenza vaccine, and the adjuvant PCPP (see e.g., Examples 5 and 7, Figures 2 and 3), the rejection is not extended to the composition of claim 3. This is because there is no suggestion in the art the claimed combination would result in the synergy demonstrated by the Applicant.

11. **(Prior Rejection- Maintained)** Claims 1, 2 5-16, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S., or Cates PCT, as applied to claims 1, 3, and 6-18 above, and further in view of Huebner, U.S. Patent 5,612,037. The Applicant traversed the rejection for substantially the same reasons as indicated in regards to the other obviousness rejections above (i.e. asserted deficiencies in the teachings of the Cates references). For the

reasons indicated above, this traversal is not found persuasive. The rejection is therefore maintained.

12. **(Prior Rejection- Maintained)** Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S., in view of Smith and Webster or in view of Huebner as applied above to claims 1, 3, and 6-18, and further in view Murry et al., Hosp. Pract. 32(7): 87-8, 91-4. The Applicant traversed the rejection for substantially the same reasons as indicated in regards to the other obviousness rejections above (i.e. asserted deficiencies in the teachings of the Cates references). For the reasons indicated above, this traversal is not found persuasive. The rejection is therefore maintained.

13. **(Prior Rejection- Maintained)** Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S., or Cates PCT, in view of Smith and Webster, or in view of Huebner as applied to claims 1, 3, 6-15, and 18 above, and further in view of Potash, U.S. 5,911,998. The Applicant traversed the rejection for substantially the same reasons as indicated in regards to the other obviousness rejections above (i.e. asserted deficiencies in the teachings of the Cates references). For the reasons indicated above, this traversal is not found persuasive. The rejection is therefore maintained.

14. **(Prior Rejection-Maintained)** Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S., in view of Smith and Webster or in view of Huebner as

applied above to claims 1, 3, and 6-18, and further in view of Hall et al., J. Infect. Dis., 163:693-698; Crowe, Vaccine, 13:415-421; Groothuis, Journal of Infectious Diseases, 177(2), pp. 467-469 (1998); and Falsey, Vaccine, 14(13), pp. 1214-1218 (1996). The Applicant traversed the rejection for substantially the same reasons as indicated in regards to the other obviousness rejections above (i.e. asserted deficiencies in the teachings of the Cates references). For the reasons indicated above, this traversal is not found persuasive. The rejection is therefore maintained.

15. **(Prior Rejection- Maintained)** Claims 1, 2, 4, 6-21 are rejected under 35 U.S.C. 103(a) as being obvious over claims 1-9, 13, 15-21, 23, and 26 of copending Application No. 09/950655 (discussed in reference to the Pre-Grant Publication of this application as PG Pub 2002/0136739), in view of Smith, Webster, Payne, and Murry. The claims and references have been described in the prior action. The Applicant traverses this rejection on substantially the same grounds as indicated above with reference to the Cates references. The rejection is therefore maintained for the same reasons as indicated above in response to these traversals, and for the reasons of record.

16. As indicated in the prior action Claims 1, 2, 4, 6-21 are not patentably distinct from claims 1-9, 13, 15-21, 23, and 26 of commonly assigned copending Application No. 09/950655 (discussed in reference to the Pre-Grant Publication of this application as PG Pub 2002/0136739). The Applicant traverses the statement that the present claims are not patentably distinct from the claims of the copending application. The rejection of claim 19 is withdrawn in

view of the cancellation of the claim. In the Response, the Applicant presents three arguments that the claimed inventions are distinct.

First, the Applicant argues that the copending application does not teach or suggest the combination of the RSV formulation with a non-virulent influenza antigen. This traversal is not found persuasive in view of the teachings of Smith and Webster, teaching that such an influenza vaccine is known in the art. Due to the suggestion of the copending application that an influenza antigen may be combined with the RSV formulation, and the fact that the currently claimed influenza antigen was known in the art, it would have been obvious to those in the art to use that antigen in the combination suggested in the copending application.

Second, the Applicant argues that claim 1 (presumably of the present application) requires that the immunogenic formulation is formulated as a vaccine for in vivo administration wherein the immunogenicity of components (a) and (b) is not impaired. The claims of the copending application also indicate that the immunogenic composition is for the in vivo administration of the composition. See claim 15. Claim 21 of the copending application also indicates that an additional "immunogen" may be used with the RSV formulation; the use of the term immunogen implying that the other immunogen has an immunogenic effect. Further, in the paragraph corresponding to paragraph 0032 of page 3 of the PG Pub, the application states that the additional immunogen is combined with the RSV formulation to result in a "polyvalent (combination)" vaccine. Thus, the application impliedly requires that, in the combination, the efficacy of the immunogens is not impaired. Finally, the copending application also teaches that the RSV formulation comprises about 100 μg of the RSV antigens. See, page 9, paragraph 0132 of the PG Pub. This amount falls within the range indicated by the pending claims. The

copending application therefore teaches a formulation within the range of the current claims, and the art teaches the use of the influenza vaccines in the currently claimed range (see the prior action). Thus, one of ordinary skill in the art that combines the teachings of the copending application with the identified art would inherently arrive at a vaccine composition with the claimed property. This argument in traversal is therefore not found persuasive.

Finally, the Applicant appeared to argue that the copending claims were distinct from the rejected claims because that the copending application does not specifically claim the presently claimed combination of immunogens. However, in claiming the combination of the RSV formulation with other immunogens generally, and in specifically identifying influenza as one of the immunogens with which the RSV formulation may be effectively combined, the copending application is clearly generic to, and renders obvious, the presently claimed invention.

As the Applicant's arguments that the claims are not patentably distinct have not been found persuasive, the Applicant is reminded as follows:

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned Application No. 09/950655, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was

made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Double Patenting

17. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

18. **(Prior Rejection- Maintained in part)** Claims 1-10, 12-16, 20, and 21 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3-11, 13-18, and 20 of copending Application No. 09/213, 770. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Because no traversal has been presented at time, the rejection is maintained.

However, the rejection of claim 3 is withdrawn in view of the unexpected (synergistic) results obtained by the particular combination of this claim.

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. **(Prior Rejection-Maintained)** Claims 1, 2, 4-16, 18, 19, 20, and 21 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, and 13 of U.S. Patent No. 6,020,182, in view of Smith et al., U.S. Patent 5,762,939 and Payne. The rejection of claim 19 is withdrawn in view of the cancellation of the claim. No traversal was presented with respect to this rejection. However, the Applicant's arguments with respect to the 103(a) rejection over the patent (as Cates U.S.) reference have been considered above. For the same reasons as indicated above, the present rejection is also maintained.

21. **(Prior Rejection-Maintained)** Claims 1, and 2, 5-21 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6-16 of U.S. Patent No. 6,309,649, in view of Smith et al., U.S. Patent 5,762,939 or Palese et al., U.S. Patent 6022726. The rejection of claim 19 is withdrawn in view of the cancellation of the claim. The Applicant traverses this rejection on substantially the same grounds as indicated

above with reference to the Cates references. The rejection is therefore maintained for the same reasons as indicated above in response to these traversals, and for the reasons of record.

22. **(Prior Rejection- Maintained)** Claims 1, 11, 15, and 17-19 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-11, 13-18, and 20 of copending Application No. 09/213, 770, or over these claims in view of Smith or Palese. The rejection of claim 19 is withdrawn in view of the cancellation of the claim. Because no traversal has been made of this provisional rejection, the rejection is maintained.

23. **(Prior Rejection-Maintained)** Claims 1, 2, 4, 6-21 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 13, 15-21, 23, and 26 of copending Application No. 09/950655 (discussed in reference to the Pre-Grant Publication of this application as PG Pub 2002/0136739), in view of Smith, Webster, Payne, and Murry. The rejection of claim 19 is withdrawn in view of the cancellation of the claim. Because no traversal has been made of this provisional rejection, the rejection is maintained.

Conclusion

24. Claim 3 is objected to as depending on rejected claims.

25. No claims are allowed.

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
December 3, 2003

JAMES HOUSEL 12/15/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600